IN THE UNITED STATES DISTRICT COURT FOR THE NORTHERN DISTRICT OF TEXAS DALLAS DIVISION

IN RE: DEPUY ORTHOPAEDICS,)
INC. PINNACLE HIP IMPLANT)
PRODUCTS LIABILITY LITIGATION	MDL DOCKET NO. 3:11-md-2244-K
This document relates to:	Civil Action No.:
CRYSTAL RUEB,))
Plaintiff,) COMPLAINT FOR DAMAGES AND JURY DEMAND
v.))
)
DEPUY ORTHOPAEDICS, INC.;	
JOHNSON & JOHNSON SERVICES, INC.;)	•
JOHNSON & JOHNSON, INC.; and DOES)
1-10, inclusive,	
Defendants.	

Plaintiff CRYSTAL RUEB, by and through undersigned Counsel, and for her Complaint against DEPUY ORTHOPAEDICS, INC, JOHNSON AND JOHNSON SERVICES, INC. and JOHNSON AND JOHNSON, INC., and DOES 1-10, INCLUSIVE (hereinafter "defendants"), allege as follows:

NATURE OF THE CASE

This product liability case is the result of a failed, untested and unapproved hip implant that was designed, manufactured, and sold by the defendants and implanted in Plaintiff CRYSTAL RUEB (hereinafter "plaintiff").

PARTIES

- 1. Plaintiff is a resident of the City of Selby, Walworth County, and is a citizen of the State of South Dakota, residing at 2810 Lincoln Avenue, Selby, South Dakota 57472.
- 2. Defendant DEPUY ORTHOPAEDICS, INC. is, and at all times relevant to this Complaint was, an Indiana corporation with its principal place of business at 700 Orthopedic Drive, Warsaw, Indiana, and is therefore deemed to be a citizen of the State of Indiana.
- 3. At all times relevant to this Complaint, DEPUY ORTHOPAEDICS, INC. designed, manufactured, tested, marketed, distributed and sold the metal-on-metal Pinnacle Hip, either directly or indirectly, to customers throughout the United States, including the plaintiff.
- 4. Defendant JOHNSON & JOHNSON SERVICES, INC., the parent company of DEPUY ORTHOPAEDICS, INC. is, and at all times relevant to this Complaint was, a New Jersey corporation with its principal place of business at One Johnson & Johnson Plaza, New Brunswick, New Jersey, and is therefore deemed to be a citizen of the State of New Jersey.
- 5. At all relevant times to this Complaint JOHNSON & JOHNSON, SERVICES, INC., as the parent of DEPUY ORTHOPAEDICS, INC., designed, manufactured, tested, advertised, marketed, distributed and sold the metal-on-metal Pinnacle Hip, either directly or indirectly, to customers throughout the United States, including the plaintiff.
- 6. Defendant JOHNSON & JOHNSON, INC. is, and at all times relevant to this Complaint was a New Jersey corporation with its principal place of business at One Johnson & Johnson Plaza, New Brunswick, New Jersey, and was the parent company of DEPUY ORTHOPAEDICS, INC.
- 7. At all relevant times to this Complaint, defendant JOHNSON & JOHNSON, INC., as the parent company of DEPUY ORTHOPAEDICS, INC., designed, manufactured,

tested, advertised, marketed, distributed and sold the metal-on-metal Pinnacle Hip, either directly or indirectly, to customers throughout the United States, including the plaintiff.

- 8. Plaintiff is unaware of the true names and capacities, whether individual, corporate, associate, or otherwise, of defendants DOES 1-10, inclusive, or any of them, and therefore sues these defendants, and each of them, by such fictitious names. Plaintiff will seek leave of this Court to amend this Complaint when the status and identities of these defendants are ascertained.
- 9. At all times relevant herein, defendants were the agents of each other, and in doing the things alleged herein, each defendant was acting within the course and scope of its agency and was subject to and under the supervision of its co-defendants.

JURISDICTION AND VENUE

- 10. Jurisdiction over this action exists under 28 U.S.C. §1332(a), based on diversity of citizenship and an amount in controversy that exceeds \$75,000 exclusive of interest and costs.
- 11. Venue in this action properly lies in this judicial district pursuant to 28 U.S.C. §1391(a) and (c), because a substantial number of events, actions or omissions giving rise to plaintiff's claims occurred in the State of South Dakota and this District.
- 12. But for the pending Multidistrict Litigation related to the product that is the subject of this litigation, venue over this action would lie in the U.S. District Court District of South Dakota.
- 13. Venue is proper in this District pursuant to Case Management Order No. 1, entered on the 29th day of June 2011, in this action [MDL Docket 3:11-MD-2244-K], Document #20, which provides, in part:

In order to eliminate delays associated with the transfer of cases in or removed to other federal district courts to this Court, and to promote judicial efficiency, any plaintiff whose case would be subject to transfer to MDL 2244 may file his or her case directly in the MDL proceedings in the Northern District of Texas.

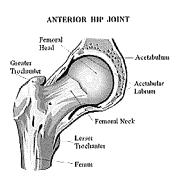
. . .

Upon completion of all pretrial proceedings applicable to a case filed directly in the Northern District of Texas, this Court may transfer the case, pursuant to 28 U.S.C. § 1404, to a court of appropriate jurisdiction for trial, based on the recommendations of the parties to that case.

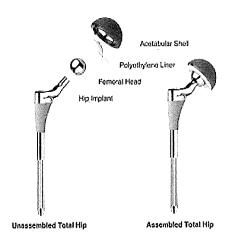
FACTUAL BACKGROUND

A. DePuy's Pinnacle Hip Is Unsafe and Has Not Been Adequately Tested

14. The hip joint is where the femur connects to the pelvis. The joint is made up of the femoral head (a ball-like structure at the very top of the femur) rotating within the acetabulum (a cup-like structure at the bottom of the pelvis.) In a healthy hip, both the femur and the acetabulum are strong and the rotation of the bones against each other is cushioned and lubricated by cartilage and fluids.



15. A total hip replacement replaces the body's natural joint with an artificial one, usually made out of metal and plastic. A typical total hip replacement system consists of four



separate components: (1) a femoral stem (labeled as "hip implant" in the diagram to the left), (2) a femoral head, (3) a plastic (polyethylene) liner, and (4) an acetabular shell.

After the surgeon hollows out a patient's femur bone, the femoral stem is implanted. The femoral head is a metal ball that is fixed on top of the femoral stem. The femoral head

forms the hip joint when it is placed inside the polyethylene liner and acetabular shell.

- 16. The Pinnacle Hip has a different design, one that puts the metal femoral ball directly in contact with a metal acetabular liner. The design of the Pinnacle Hip was not sufficiently tested by the defendants, and it was never approved by the FDA as being safe or effective for the products' intended purpose.
- 17. The Pinnacle Hip is a Class III medical device. Class III devices are those that operate to sustain human life, are of substantial importance in preventing impairment of human health, or pose potentially unreasonable risks to patients.
- 18. The Medical Device Amendments to the Food, Drug, and Cosmetics Act of 1938 ("MDA"), in theory, require Class III medical devices, including the Pinnacle Hip, to undergo premarket approval by the FDA, a process which obligates the manufacturer to design and implement a clinical investigation and to submit the results of that investigation to the FDA.
- 19. Premarket approval is a rigorous process that requires a manufacturer to submit what is typically a multivolume application that includes, among other things, full reports of all studies and investigations of the device's safety and effectiveness that have been published or should reasonably be known to the applicant; a full statement of the device's components, ingredients, and properties and of the principle or principles of operation; a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and, when relevant, packing and installation of, such device; samples or device components required by the FDA; and a specimen of the proposed labeling.
- 20. The FDA may grant premarket approval only if it finds that there is reasonable assurance that the medical device is safe and effective and must weigh any probable benefit to health from the use of the device against any probable risk of injury or illness from such use.

- 21. A medical device on the market prior to the effective date of the MDA a so-called "grandfathered" device was not required to undergo premarket approval.
- 22. In addition, a medical device marketed *after* the MDA's effective date may bypass the rigorous premarket approval process if the device is "substantially equivalent" to a "grandfathered" pre-MDA device (*i.e.*, a device approved prior to May 28, 1976). This exception to premarket approval is known as the "510(k)" process and simply requires the manufacturer to notify the FDA under section 510(k) of the MDA of its intent to market a device at least 90 days prior to the device's introduction on the market, and to explain the device's substantial equivalence to a pre-MDA predicate device. The FDA may then clear the new device for sale in the United States.
- 23. The MDA does not require an FDA determination that the device is in fact, substantially equivalent to a grandfathered device.
- 24. Instead of assuring the safety of the Pinnacle Hip through clinical trials, DePuy sought to market its Pinnacle Hip without conducting any clinical trials by obtaining FDA approval under section 510(k). To that end, defendants submitted a section 510(k) premarket notification of intent to market the Pinnacle Hip.
- 25. By telling the FDA that the Pinnacle Hip's design was "substantially equivalent" to other hip products on the market, DePuy was able to avoid the safety review required for premarket approval under FDA regulations including clinical trials.
- 26. The FDA cleared the Pinnacle Hip for sale by means of the abbreviated 510(k) process and consequently, the FDA did not require the Pinnacle Hip to undergo clinical trials.

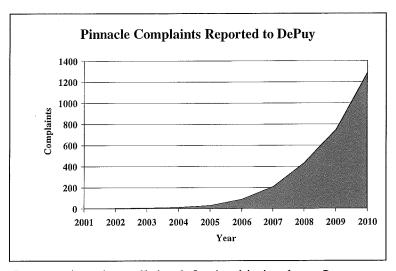
- 27. The 510(k) notification for the Pinnacle Hip includes only defendant DePuy's assertion that it believes the DePuy Pinnacle Hip to be substantially equivalent to devices that themselves had never been reviewed for safety and effectiveness.
- 28. Significantly, unlike the premarket approval process, the 510(k) notification process does not call for scrutiny or even clinical testing of a device's safety and effectiveness.
- 29. A finding of substantial equivalence is not equivalent to a finding of a device's safety and effectiveness. This point is forcefully underscored by the FDA's letter to DePuy, which says nothing about the safety and effectiveness of the Pinnacle Hip; finds only that the device was "substantially equivalent to devices introduced into interstate commerce prior to May 28, 1976"; and concludes by stressing that the agency's determination of substantial equivalence "does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies."
- 30. Thus, the FDA's finding of "substantial equivalence" had nothing to do with reviewing the Pinnacle Hip's safety and effectiveness, but rather only a determination of equivalence to devices that themselves underwent no safety and effectiveness review.
- 31. While most hip replacements use a polyethylene *plastic* acetabular liner, DePuy's Pinnacle Hip has a critical difference: it uses a *metal* acetabular liner. By using a metal acetabular liner and a metal femoral ball, the Pinnacle Hip forces metal to rub against metal with the full weight and pressure of the human body. Because of defendants' defective design for the Pinnacle Hip, hundreds of patients have been forced to undergo surgeries to replace the failed hip implants.

32. Plaintiff believes that the Pinnacle Hip suffers from a similar design or manufacturing defect that forced DePuy to recall over 93,000 metal-on-metal ASR and ASR XL hip implants. While the exact nature of the common defect is still being investigated, plaintiff believes that both hip implants suffer from one or more similar design or manufacturing defects that cause excessive amounts of cobalt and chromium to wear from the surface of the acetabular insert or from the femoral head. These cobalt and chromium fragments prompt the body to react by rejecting the hip implant. This rejection often manifests with symptoms of pain, looseness, dislocation, and squeaking and popping sounds. Inside the hip joint, the metal reaction often causes fluids to accumulate and soft tissues and bone to die.

B. DePuy Should Have Recalled The Pinnacle Hip Years Ago; Over 1,300 Adverse Events Related To The Pinnacle Hip Have Been Reported

- 33. It wasn't long after DePuy launched the Pinnacle Hip that reports of failures began flooding into DePuy. For example, on May 4, 2002, DePuy received a complaint that a patient had to undergo a surgery to remove and replace the hip implant because the liner disassociated with the cup. DePuy closed its investigation of this complaint, finding that "corrective action is not indicated." Two weeks later, on May 17, 2002, DePuy received another report that another patient had to undergo surgery to remove and replace a defective hip implant because the acetabular cup had loosened. Again, DePuy closed its investigation of this complaint, finding that "corrective action is not indicated."
- 34. DePuy would go on to receive hundreds of similar complaints reporting that the Pinnacle Hip had failed due to premature loosening of the acetabular cup and that the failure had forced patients to undergo painful and risky surgeries to remove and replace the failed hip component.

- 35. To date, DePuy has received an astonishing *1,300 reports* associated with Pinnacle Hips.
- 36. Despite its knowledge that the Pinnacle Hip had a defect and that it had failed hundreds of times, causing hundreds of patients to



undergo the agony of another surgery, DePuy continued to sell the defective hip implant. In so doing, DePuy actively concealed the known defect from doctors and patients—including plaintiff and plaintiff's doctor(s)—and misrepresented that that the Pinnacle Hip was a safe and effective medical device.

DePuy's reason to conceal the defect in its Pinnacle Hip is clear. In 2009 alone, DePuy brought in more than \$5.4 billion in sales. Hip implant sales are critically important to DePuy's parent company, Johnson & Johnson, and DePuy is one of Johnson & Johnson's most profitable business groups. In 2008, DePuy was faced with a critical defect in one of its hip implant system. The last thing DePuy wanted to do was to admit that these popular products had a critical defect that could cause a premature failure, forcing patients to have to undergo another painful surgery. Focused on corporate profits, and at the expense of patient safety, DePuy decided that it would not issue an embarrassing recall when it learned of the defects with its Pinnacle Hip. Moreover, motivated by greed rather than patient safety, DePuy did not even stop selling the Pinnacle Hip. Instead, it continued to manufacture the hip implants and it continued to sell them to unsuspecting patients, including the plaintiff. To this day, DePuy continues to sell

these defective implants to unsuspecting patients without any warning about the risks or the failures that have been reported to the company.

C. Plaintiff's Pinnacle Hip Caused Plaintiff to Undergo A Painful And Risky Surgery.

38. On or around June 6, 2007, plaintiff underwent a surgical procedure at Poudre Valley Health System in Fort Collins, Colorado, where a DePuy Pinnacle metal-on-metal hip was implanted in plaintiff's right side by Roger Sobel, M.D. The following DePuy Pinnacle components were implanted:

DePuy Size: 52mm Pinnacle Press-Fit Acetabular Cup DePuy Orthopaedics, Inc.

P.O. Box. 988 Warsaw, IN 46581

DePuy Size: 36mm

Metal Femoral Head DePuy Orthopaedics, Inc. 700 Orthopaedic Drive Warsaw, IN 46580

DePuy Size: 52mm OD

Pinnacle Metal Liner DePuy Orthopaedics, Inc. 700 Orthopaedic Drive Warsaw, IN 46582

- 39. Subsequently, plaintiff began to experience adverse symptoms related to her right hip implant including, but not limited to the following: severe pain and discomfort in and around her right hip; considerable pain in the anterior medial right hip area; elevated metal ions; and emotional distress normally expected in an injury of this nature.
- 40. On March 2, 2014, plaintiff's right hip was revised at Sanford Medical Center Fargo in Fargo, North Dakota, by Gary Matthys, M.D. The DePuy Pinnacle metal-on-metal hip device was removed and replaced with a non metal-on-metal device.

- 41. Having to go through an additional surgery/revision has left plaintiff with much greater risks of future complications than plaintiff had before the revision surgery. For example, several studies have found that just one revision surgery causes a much higher risk of dislocation compared with an original hip replacement surgery. In one study conducted by Charlotte Phillips and her colleagues at Brigham and Women's Hospital in Boston, 14.4 percent of patients who underwent a revision surgery suffered from a dislocation compared with 3.9 percent of patients who underwent an original hip replacement surgery. In other words, hip replacement patients who have undergone a revision surgery are almost four times more likely to suffer from a hip dislocation than those who have not. (Phillips CB, et al. Incidence rates of dislocation, pulmonary embolism, and deep infection during the first six months after elective total hip replacement. American Journal of Bone and Joint Surgery 2003; 85:20–26.)
- 42. As a direct and proximate result of plaintiff's defective Pinnacle Hip and the defendants' wrongful conduct, plaintiff sustained and continues to suffer economic damages (including lost wages, medical and hospital expenses), severe and possibly permanent injuries, pain, suffering and emotional distress. As a result, plaintiff has sustained and will continue to sustain damages in an amount to be proven at trial, but which will far exceed the jurisdictional minimum of this court.

FIRST CAUSE OF ACTION

(Strict Product Liability) Against All Defendants

43. Plaintiff incorporates by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further allege as follows:

- 44. Defendants designed, manufactured, promoted, distributed, marketed, and sold the DePuy Pinnacle Hip, including the Pinnacle acetabular cup, the Pinnacle metal liner, and the femoral head.
- 45. At all times material hereto, the DePuy Pinnacle Hip that was designed, manufactured, promoted, distributed, marketed, and sold by the defendants was expected to reach, and did reach, prescribing physicians and consumers, including plaintiff, without substantial change in the condition in which it was sold.
- 46. At all times material hereto, the DePuy Pinnacle Hip that was designed, manufactured, promoted, distributed, marketed, and sold by the defendants was in a defective and unreasonably dangerous condition at the time it was placed in the stream of commerce. Such condition included, but is not limited to, one or more of the following particulars:
- (a) When placed in the stream of commerce, the DePuy Pinnacle Hip contained manufacturing defects, subjecting plaintiff and others to risks, including the risk that the acetabular component would not properly grow into the bone, causing the hip system to prematurely fail and requiring a complex, risky, and painful surgery to remove and replace the defective product;
- (b) When placed in the stream of commerce, the DePuy Pinnacle Hip contained unreasonably dangerous design defects and was not reasonably safe for the intended use, subjecting plaintiff and others to risks, including the risk that (1) the acetabular component would not properly grow into the bone, causing the hip system to prematurely fail and requiring a complex, risky, and painful surgery to remove and replace the defective product, and (2) the Pinnacle Hip would fail early and expose plaintiff to the unreasonable risk of toxic metals, metallosis, and multiple revision surgeries;

- (c) The DePuy Pinnacle Hip was insufficiently tested; and/or
- (d) The DePuy Pinnacle Hip was not accompanied by adequate instructions and/or warnings to fully inform plaintiff or plaintiff's physicians of the full nature or extent of the risks associated with its use.
- 47. Defendants knew or should have known of the dangers associated with the use of the DePuy Pinnacle Hip, as well as the defective nature of the DePuy Pinnacle Hip. Despite this knowledge, defendants continued to manufacture, sell, distribute, promote and supply the DePuy Pinnacle Hip so as to maximize sales and profits at the expense of the public health and safety. Defendants' conduct was done in conscious disregard of the foreseeable harm caused by the DePuy Pinnacle Hip and in conscious disregard for the rights and safety of plaintiff and other consumers.
- 48. Plaintiff and plaintiff's physician(s) used the DePuy Pinnacle Hip as directed for its intended purpose.
- 49. At all times herein mentioned, the DePuy Pinnacle Hip was defective, and defendants knew that it was to be used by the user without inspection for defects therein.

 Moreover, neither plaintiff nor plaintiff's physician(s) knew or had reason to know at the time of the use of the subject products, of the existence of the aforementioned defects. Neither plaintiff nor her physician(s) could have discovered the defects in the DePuy Pinnacle Hip through the reasonable exercise of care.
- 50. The DePuy Pinnacle Hip had not been materially altered or modified prior to its implantation in plaintiff.
- 51. As a direct and proximate result of the failure of the defective DePuy Pinnacle Hip, plaintiff has suffered the injuries and damages as described herein.

SECOND CAUSE OF ACTION

(Negligence) Against All Defendants

- 52. Plaintiff incorporates by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further allege as follows:
- 53. At all times herein mentioned defendants had a duty to exercise reasonable care in the design, manufacture, testing, inspection, labeling, and sale of the DePuy Pinnacle Hip to ensure that it would be safely used in a manner and for a purpose for which it was made.
- 54. Defendants maliciously, recklessly and/or negligently failed to exercise ordinary care in the design, manufacture, testing, advertising, marketing, and sale of the DePuy Pinnacle Hip.
- 55. Defendants maliciously, recklessly and/or negligently failed in their duty to exercise reasonable care in the provision of an adequate warning to plaintiff and plaintiff's physician(s) as to the risks of the DePuy Pinnacle Hip.
- 56. Defendants maliciously, recklessly and/or negligently failed to exercise reasonable care in the post-marketing warnings as to the risks of the DePuy Pinnacle Hip when they knew or should have known of said risks.
- 57. As a result of defendants' wrongful conduct, plaintiff has suffered injuries and damages as alleged herein.

THIRD CAUSE OF ACTION

(Negligent Misrepresentation) Against All Defendants

- 58. Plaintiff incorporates by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further allege as follows:
- 59. The defendants supplied false information to the public, to plaintiff and to plaintiff's physician(s) regarding the high-quality, safety and effectiveness of the Pinnacle Hip.
- 60. Defendants provided this false information to induce the public, plaintiff and plaintiff's physician(s) to purchase and implant a Pinnacle Hip.
- 61. The defendants knew or should have known that the information they supplied regarding the purported high-quality, safety and effectiveness of the implant to induce plaintiff and plaintiff's physician(s) to purchase and use a Pinnacle Hip was false.
- 62. The defendants were negligent in obtaining or communicating false information regarding the purported high-quality, safety and effectiveness of the Pinnacle Hip.
- 63. Plaintiff and plaintiff's physician(s) relied on the false information supplied by the defendants to their detriment by causing the Pinnacle Hip to be purchased and implanted in plaintiff.
- 64. Plaintiff and plaintiff's physician(s) were justified in their reliance on the false information supplied by the defendants regarding the purported high-quality, safety and effectiveness of the Pinnacle Hip.
- 65. As a direct and proximate result of defendants' negligent misrepresentations, plaintiff has suffered significant damages, including, but not limited to, permanent physical injury, economic loss, pain and suffering and the need for a revision surgery to repair the physical damage to plaintiff caused by the Pinnacle Hip.

FOURTH CAUSE OF ACTION

(Breach of Implied Warranties)
Against All Defendants

- 66. Plaintiff incorporates by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further alleges as follows:
- 67. Prior to the time that the DePuy Pinnacle Hip was used by plaintiff, defendants impliedly warranted to plaintiff and plaintiff's physician(s) that the DePuy Pinnacle Hip was of merchantable quality and safe and fit for the use for which it was intended.
- 68. Plaintiff and plaintiff's physician(s) were and are unskilled in the research, design and manufacture of the DePuy Pinnacle Hip, and they reasonably relied entirely on the skill, judgment and implied warranty of defendants in using the DePuy Pinnacle Hip.
- 69. The DePuy Pinnacle Hip was neither safe for its intended use nor of merchantable quality, as warranted by defendants, in that it had dangerous propensities when put to its intended use and would cause severe injuries to the user.
- 70. Defendants, by selling, delivering and/or distributing the defective DePuy Pinnacle Hip to plaintiff breached the implied warranty of merchantability and fitness and caused plaintiff to suffer severe pain and emotional distress, incur medical expenses and incur a loss of earning capacity.
- 71. As a result of the aforementioned breach of implied warranties by defendants, plaintiff has suffered injuries and damages as alleged herein.

FIFTH CAUSE OF ACTION

(Breach of Express Warranty) Against All Defendants

- 72. Plaintiff incorporates by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further allege as follows:
- 73. At all times herein mentioned, defendants expressly warranted to plaintiff and plaintiff's physician(s), by and through statements made by defendants or their authorized agents or sales representatives, orally and in publications, package inserts and other written materials intended for physicians, medical patients and the general public, that the aforementioned DePuy Pinnacle Hip was safe, effective, fit and proper for its intended use.
- 74. In utilizing the aforementioned DePuy Pinnacle Hip, plaintiff and plaintiff's physician(s) relied on the skill, judgment, representations and foregoing express warranties of defendants.
- 75. Said warranties and representations were false in that the aforementioned DePuy Pinnacle Hip was not safe and was unfit for the uses for which it was intended.
- 76. As a result of the foregoing breach of express warranties by defendants, plaintiff has suffered injuries and damages as alleged herein.

SIXTH CAUSE OF ACTION

(Fraud) Against All Defendants

- 77. Plaintiff incorporates by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further alleges as follows:
- 78. Defendants made representations to plaintiff and plaintiff's physician(s) that their Pinnacle Hip is a high-quality, safe and effective hip replacement system.

- 79. Before they marketed the Pinnacle Hip that was implanted in plaintiff, defendants knew or should have known of the unreasonable dangers and serious health risks that such a metal-on-metal total hip replacement system posed to patients like plaintiff.
- 80. As specifically described in detail above, defendants knew that the Pinnacle Hip subjected patients to early failure, painful and harmful physical reactions to toxic metallic particles and ions, death of tissue, bone loss and the need for explants and revision surgery.
- 81. Defendants' representations to plaintiff and plaintiff's physician(s) that their Pinnacle Hip was high-quality, safe and effective were false.
- 82. Defendants concealed their knowledge of the unreasonable risks and dangers associated with the use of the Pinnacle Hip to induce plaintiff and many thousands of others to purchase the system for surgical implantation in their bodies.
- 83. Neither plaintiff nor plaintiff's physician(s) knew of the falsity of defendants, statements regarding the Pinnacle Hip.
- 84. Plaintiff and plaintiff's physician(s) relied upon and accepted as truthful defendants' representations regarding the Pinnacle Hip.
- 85. Plaintiff and plaintiff's physician(s) had a right to rely on defendants' representations and in fact did rely upon such representations. Had plaintiff known that the Pinnacle Hip would fail early and expose plaintiff to the unreasonable risk of toxic metals, metallosis, and multiple revision surgeries, plaintiff would not have purchased or allowed the Pinnacle Hip to have been surgically implanted.
- 86. As a direct and proximate result of defendants' fraudulent representations, plaintiff has suffered significant damages, including, but not limited to, permanent physical injury, economic loss, and pain and suffering caused by the Pinnacle Hip.

SEVENTH CAUSE OF ACTION

(Punitive Damages) Against All Defendants

- 87. Plaintiff incorporates by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further allege as follows:
- 88. Through their actions as described herein, Defendants consciously, intentionally, and/or deliberately disregarded the rights and safety of Plaintiff CRYSTAL RUEB and others.
 - 89. Accordingly, plaintiff is entitled to punitive damages.

PRAYER FOR RELIEF

WHEREFORE, plaintiff demands judgment for the following:

- 1. Past and future medical and incidental expenses, according to proof;
- 2. Past and future loss of earnings and/or earning capacity, according to proof;
- 3. Past and future compensatory damages, including but not limited to pain and suffering for severe and permanent injuries, according to proof;
- 4. Punitive and exemplary damages in an amount to be determined at trial;
- 5. Prejudgment and post judgment interest;
- 6. Attorneys' fees and costs to bring this action; and
- 7. Such other and further relief as the court may deem just and proper.

JURY AND TRIAL DEMANDED

Please take notice that plaintiff hereby demands a trial by jury as to all issues in the above matter.

Dated this 1st day of April 2015.

Respectfully submitted,

s/Seth A. Katz
Seth A. Katz
Peter W. Burg
BURG SIMPSON
ELDREDGE HERSH & JARDINE, P.C.

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